

REMARKS

By this amendment, Applicant cancels all claims previously withdrawn from consideration by the Examiner, namely claims 108, 134-136, 140, 143, 144, 150, 176-178, 182.

Claims 102 and 141 stand rejected under 35 U.S.C. 112, ¶1 for lack of written description. Claims 102-107, 109-133, 137-139, 141, 142, 145-149, 151-175 and 179-191 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Bao et al. (U.S. 6,224,630) in view of Gilson (U.S. 5,904,703).

The rejections are respectfully traversed.

Rejection under 35 U.S.C. § 112, ¶1

Claims 102 and 141 stand rejected under 35 U.S.C. 112, ¶1 for lack of written description. The Examiner states that the claims, in reciting “at least one extension” are not described in the specification, which contains an illustrative embodiment having two extensions. The Examiner suggests that “at least one” includes embodiments having only one extension, and that the specification does not describe such an embodiment.

Applicants respectfully traverse the rejection. It is respectfully submitted that Applicants need not show *literally* the invention as presently claimed in the specification to fully meet the written description requirement. To comply with the written description requirement, an application must reasonably convey to persons skilled in the art that, as of the filing date thereof, the inventor had possession of the subject matter later claimed by him. *In re Driscoll*, 195 USPQ 434 (CCPA 1977). Applicants believe that this requirement has been more than met, and that Applicants have provided sufficient written support for the limitations.

Notwithstanding, Applicants have amended claims 102 and 141 without disclaimer to simply recite “an extension” without further limitation as to the total number of extensions.

The Examiner is respectfully requested to reconsider and withdraw the present rejection.

Rejection under 35 U.S.C. § 103(a)

Claims 102-107, 109-133, 137-139, 141, 142, 145-149, 151-175 and 179-191 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Bao et al. (U.S. 6,224,630) in view of Gilson (U.S. 5,904,703).

The Examiner explains that Bao et al., which teaches an expandable plug for sealing an annular aperture, can take a spool shape. The Examiner also states that the spool ends disclosed by Bao et al. are not deflectable, as required by the claims. The Examiner goes on to explain that Gilson, who teaches a Tran catheter vascular occlusion device (e.g., for septal defect occlusion), shows deflectable extensions. The Examiner concludes that it would have been obvious for one having ordinary skill in the art to “look to the teachings of Gilson to modify the device of Bao et al. by including first and second extensions (72) that lie in the same reference plane when undeflected in order to facilitate the collapsing of the device for delivery through the cannula.”

The rejection is respectfully traversed because the Examiner has failed to establish a *prima facie* case of obviousness, for at least the reason that the references do not provide a factual motivation to combine.

A rejection based on Section 103 must rest on a factual basis, with the facts being interpreted without hindsight reconstruction of the invention from the prior art. *See Ex Parte Hammond*, 41 USPQ.2d 1217 (Bd. Pat. App. &Int. 1996). In making this evaluation, the examiner has the initial duty of supplying the factual basis for the rejection she advances. She may not, because she doubts that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in the factual basis. *See In re Warner*, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967), *cert. denied*, 389 U.S. 1057 (1968).

The Examiner cites Bao as the primary reference, which discloses a device for plugging a hole in an annulus. Throughout Bao's specifications, the invention is described as a "plug" - an expandable device adapted to be sealably positioned within an annular aperture. Applicant points to the following definition from the American Heritage College Dictionary:

plug 1. an object, such as a cork, used to fill a hole tightly; a stopper.

Bao mentions a "spool" shape with enlarged end portions as an unillustrated alternative embodiment of his annular plug. Col. 7, ll. 61-67. It is respectfully submitted from the onset that one having ordinary skill in the art would not look outside the teaching of Bao, because Bao has articulated radial expansion as the means for sealing his plug device in an annular defect. The Examiner points to no reason at all why any modification of the Bao device would be obvious to achieve the repair function of the disclosed Bao plug.

Notwithstanding, and based on the minimal reference in Bao to a spool shape, the Examiner combines Bao with Gilson, a transcatheter vascular occlusion device (e.g., for septal defect occlusion). Fig. 14 of Gilson, as referred to by the Examiner, discloses large “discs” (4, 5) that extensively cover the tissue on either side of a vascular aperture (e.g., septal defect). By the very nature of the size of these disks with respect to the defect, Gilson describes folding the discs to perform transcatheter delivery of the device to the defect. The Examiner suggests that one having ordinary skill in the art would combine the exaggerated “spool shape” device having large, deflectable disks (as described by Gilson) with the intervertebral disc annulus plug of Bao et al.

The fundamental problem with this argument is illustrated by the Gilson reference itself. Fig. 12 of Gilson depicts an alternative embodiment of an occluder device that is more like a plug and more similar to what is described by Bao. And, just like Bao, Gilson does not teach combining the plug embodiment with any other structure, including the deflectable disks of Fig. 14, as suggested by the Examiner. Who would have been better able, or motivated, than Gilson himself to combine these inventions if it were indeed obvious and of some benefit?

It is respectfully submitted that the Gilson reference would not provide motivation to one having ordinary skill in the art to combine the features in the way suggested by the Examiner for the simple reason that Gilson obviously failed to recognize the combination. Contrary to the Examiner’s allegation of obviousness, Gilson treats the plugging (Figs. 12 and 13) and sealing disc (Fig. 14) concepts as substantially separate approaches.

In the rejection, the Examiner goes on to justify the combination of Bao and Gilson by citing to a problem created by the combination itself. Specifically, the Official Action states that the large lateral extensions resulting from combining Gilson with Bao would motivate one having ordinary skill in the art to make the lateral extensions foldable. But there still exists the question of why one having ordinary skill in the art would make the combination at all.

Bao et al. disclose that their plug device may have a spool shape. Col. 7, ll. 61-67. Notwithstanding this optional feature, the plug device is described as being radially expansible *in situ* after delivery. See Col. 13, ll. 38-55. Delivery, as described by Bao et al. is generally either surgical (Col. 13, ll. 38-44) or through the lumen of a cannula while in a collapsed state (Col. 11, ll. 1-12; Col. 14, ll. 1-11 and 51-65).

What Bao et al. do not disclose is large disks creating an exaggerated “spool shape” such as that taught by Gilson, and the reason for this is because Bao et al. teach a plug that is held in place by taught circumferential engagement with the aperture wall. Col. 11, ll. 58-64. This is not the same sealing mechanism relied on by the transcatheter vascular (e.g., septal defect) occlusion device taught by Gilson In Fig. 14. The device of Fig. 14 does not and cannot rely primarily on taught circumferential engagement within the aperture walls of a septal defect to resist expulsion, because the cardiac septum itself is so thin. So, rather than rely on the taught circumferential engagement of the aperture taught by Bao et al., Gilson relies on a “button” approach where the aperture is sealed by relatively large, overlying disc members (4, 5), which are connected through the aperture by a narrowed neck portion (6) reinforced with a tubular sleeve (11). The neck portion is not the principal sealing means, as is with Bao

et al., it is merely to connect and hold the “buttons” together on opposite sides of the septal defect. This is evident because tubular sleeve (11) is hollow and needs to be minimized so as to minimize blood shunting across the septum.

The differences between the functions of the bodies and the end portions of the Bao et al. device vis-à-vis the Gilson device are dramatic. The body of Bao et al. is the retaining and sealing member; whereas the neck of Gilson is primarily to connect the disc portions. The end portions of Bao are merely ancillary features intended to further help resist expulsion of the device; whereas the disc portions of Gilson are the primary retaining and sealing means.

To further elucidate the differences, the Gilson patent speaks to the relative dimensions of the body vis-à-vis the disc portions, stating that in deflecting the discs as shown in Fig. 14, the disks are folded to essentially form an extension of the neck portion to permit catheter deployment. Col. 6, ll. 16-23. It is not seen how this could be achieved in combination with Bao. As shown in Fig. 1 of Bao, the plug 10 is already of a diameter substantially equal to the height of the disk. Naturally, the larger the circumference of the body of the Bao plug, the greater the contact with the aperture, and the greater the resulting fixation. Bao “spool shape” extensions are neither described as deflectable, nor are they necessary. Were any “spool” extensions attached to the plug which were of a size requiring deflection and collapsing into a compact form of the type shown by Gilson, the extensions would *vastly* exceed the height of the disc *in situ*. This is clearly not what is intended by Bao et al. and, to the contrary, would pose significant clinical risks to the surrounding structures, such as the vertebral bodies.

Therefore, one having ordinary skill in the art would not have found it obvious to combine the disk portions of Gilson with the plug of Bao et al., nor would he or she be motivated to do so. Withdrawal of the rejection is therefore respectfully requested.

Dependent claims 103-107, 109-133, 137-139, and 142, 145-149, 151-175 and 179-191 depend from independent claims 102 and 141, and are allowable for at least the same reasons as set forth above. Indication of allowability by the examiner is respectfully requested.

Accordingly, it is respectfully submitted that the instant claims are allowable over Wardlaw in view of Bao, early indication of which is requested.

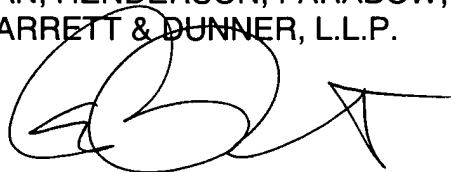
Conclusion

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

A handwritten signature in black ink, appearing to read 'ERACITI', with a stylized flourish extending to the right.

Date: February 24, 2006

By:

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